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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,426	11/13/2001	Helle Woldike	5565.214-US	3262

7590 05/20/2002

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EXAMINER	
MARVICH, MARIA	
ART UNIT	PAPER NUMBER
1636	6

DATE MAILED: 05/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,426	WOLDIKE ET AL.	
	Examiner	Art Unit	
	Maria B. Marvich	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 November 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/558,027* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification/Informalities

The disclosure is objected to because of the following informalities: A large blank section appears in the specification at page 9.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1-4 and 7-10 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-6 of U.S. Patent No.6,329,176. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite the same methods for the production of Factor VII. The independent claim in the 6,329,176 patent is more narrow in scope than the instant claims with the claims in the 6,329,176 patent reading on a method comprising a mammalian host cell comprising a DNA sequence encoding yeast KEX2 endoprotease and the instant claims recite a method utilizing a yeast-derived endoprotease having Kex2 enzymatic activity (claim 1) that is a Kex2-like

endoprotease (claim 3). Both the dependent claims in the 6,329,176 patent and the instant claim recite a method for producing Factor VII in a mammalian cell including CHO, BHK, HEK 2993 wherein the culture medium is a serum free medium . The instantly claimed subject matter is encompassed within the claims of the 6,329,176 patent. It would have been obvious to one of ordinary skill to take the claims from patent 6,329,176 to generate the instant invention because the claims in 6,329,176 patent recite the same methodologies for producing Factor VII utilizing Kex2 enzymatic activity. The ordinary skilled artisan would have been motivated to do this due to the success recited in the claims of US patent 6,329,176 utilizing Kex2. Given the teachings of the claims in 6,274,354 and the level of skill of the ordinary skilled artisan at the time of the invention, a reasonable expectation of success in practicing the claimed invention for Factor VII production would have been expected.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the 6,329,176 patent, then two different assignees would hold a patent to the claimed invention of 6,329,176, and thus improperly there would be possible harassment by multiple assignees.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim reads on a genus of yeast-derived endoproteases having Kex2 enzymatic activity or "Kex2 like" endoproteases and methods of using endoprotease for the production of Factor VII through cultivation of mammalian cell lines co-expressing Factor VII and said endoprotease. Applicants provide a written description for *S. cerevisiae* Kex2 and C-terminally truncated *S. cerevisiae* Kex2 endoprotease.

The written description requirement for genus claims may be satisfied through sufficient description of a relevant a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics such as structure or other physical and/or chemical properties, by functional characteristics couple with a known or disclosed correlation between function and structure or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, applicants present working examples for *S. cerevisiae* Kex2 and provide disclosures of two C-terminally truncated Kex2 molecules of to amino acid 614 or 675 from 814. Applicants provide no relevant identifying characteristics of other Kex2 endoproteases with the same activity of claimed invention. It must be considered that any yeast-derived endoprotease having Kex2 enzymatic activity must be empirically determined. It must be considered that the disclosed example (C-terminal truncated Kex2) is not a representative number of species to show applicants were in possession of the claimed genus. It must be assumed that the skilled artisan would not conclude that applicant was in possession of claimed genus.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucell, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst Kay Pinkney whose telephone number is (703) 305-3553.

Maria B Marvich, PhD
Examiner
Art Unit 1636

May 16, 2002

DAVID GUZO
PRIMARY EXAMINER